

09/921,682

-2-

PD-5801-D1-01-KD

present application are patentably distinct from Claim 1 of U.S. Patent 6,306,910. However, in order to expedite prosecution of such claims, they have attached to this document a terminal disclaimer, which disclaims term of any patent issuing from the present application that extends beyond the term of U.S. Patent 6,306,910. In view of their submission of the attached terminal disclaimer, Applicants respectfully request that the above rejection be withdrawn.

In the Office Action, the Examiner also rejected Claims 1-5 under 35 U.S.C. §103(a) as being unpatentable over Ehrenberg et al., *Neurology*, Vol. 48, No. 3, SUPPL. 2, pp. A278-A279 ("Ehrenberg"), which refers to the use of gabapentin for the treatment of periodic limb movements. The Examiner took the position that periodic limb movements is a sleep disorder that results in insomnia and that one skilled in the art would have been motivated, based on Ehrenberg's teaching, to administer gabapentin to treat insomnia of various etiologies. For the reasons that follow, Applicants respectfully traverse this rejection and request that it be withdrawn.

Periodic limb movement disorder (PLMS or PLMD) is distinct from insomnia. It is a very specific sleep disorder that is most common in the elderly. It may be caused by administration of monoamine oxidase inhibitors and may be associated with some neurological metabolic conditions, sleep apnea, and narcolepsy. *Id.* at 760. PLMS is characterized by repetitive stereotyped movements of the lower extremities occurring every 10-120 seconds during sleep. *Lexicon Psychiatry, Neurology, and the Neurosciences*, edited by Frank J. Ayd, Jr., Second Edition, Lippincott William & Wilkins, 2000. Chronic insomnia may be secondary to PLMS. *Id.* at 525. Thus, PLMS may result in insomnia, but does not necessarily result in insomnia. Moreover, secondary insomnias are preferably treated by treating the underlying cause of the insomnia rather than by treating the insomnia symptom. *Id.* at 526. In view of the above, Applicants submit that those of skill in the art having knowledge that a particular drug, e.g., gabapentin, is useful for the treatment of PLMS would have no reason to expect that the same drug would be useful for the treatment of insomnia. At most, they would find it obvious to try treating insomnia with that drug.

09/921,682

-3-

PD-5801-D1-01-KD

Insomnia, which can be defined as difficulty initiating or maintaining sleep, is a very broad category that includes many sleep disorders that vary to a substantial degree not only in their severity and duration, but also in their diagnostic criteria and methods of treatment. Examples of such disorders are acute insomnia, chronic insomnia, initial insomnia, persistent insomnia, primary insomnia, rebound insomnia, secondary insomnia, transient insomnia, middle insomnia, and insomnia phobia. *Id.* at 524-526.

Contrary to the Examiner's position, treatments for insomnia vary substantially with the type of insomnia the patient is experiencing. For example, patients with initial insomnia (difficulty falling asleep during the first few hours of the sleep period) require only a short acting hypnotic such as triazolam or zolpidem, while patients with initial insomnia and nocturnal awakening benefit most from an intermediate acting benzodiazepine such as lorazepam, estazolam or temezepam. *Id.* at 525. Short-term, intermittent use of hypnotics and sedatives tricyclic antidepressants may be useful for temporary problems resulting in insomnia, such as bereavement, dislocation and situational anxiety. *Id.* at 524. However, there are no studies that demonstrate the long-term effectiveness. *Id.* Patients suffering from primary insomnia (sleep dysfunction caused by disruption of the sleep mechanisms in the brain) may need long-term treatment with hypnotic drugs. In addition to sedatives/hypnotic medicines, the following have been reported useful for insomnia: progressive relaxation training, electromyography, theta or sensory motor rhythm (SMR); biofeedback training; behavioral therapies, including stimulus controlled and speech restriction therapy; and therapies for insomnia with clear organic ideologies, such as nasal continuous positive airway pressure for sleep apnea. *Id.* at 524-525. Applicants respectfully submit that the variability in the types of insomnia and treatments for insomnia further supports Applicants position that knowledge of the use of a particular drug, e.g., gabapentin, for the treatment of PLMS, a disorder that is distinct from insomnia and to which insomnia may be secondary, would not lead one of skill in the art to have even a reasonable expectation that the same drug would be efficacious for the treatment of insomnia.

FROM WARNER-LAMBERT CO.

(TUE) 05. 21' 02 15:36/ST. 15:33/NO. 3560555374 P 11

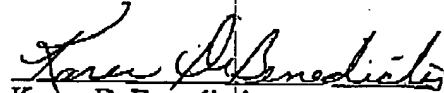
09/921,682

-4-

PD-5801-DJ-01-KD

In view of the above, Applicants respectfully request that the foregoing rejection under 35 U.S.C. §103 be withdrawn and Claims 1-5 be allowed to issue.

Respectfully submitted,



Karen DeBenedictis

Reg. No. 32,977

Warner-Lambert Company

2800 Plymouth Road

Ann Arbor, MI 48105

Tel. (734) 622-3374

Fax (734) 622-1553

KD1P4072.doc